

Laparoscopic Gastric Banding

A Prospective, Randomized Study Comparing the Lapband and the SAGB: Early Results

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Objective: The objective of this study was to evaluate the results of laparoscopic gastric banding using 2 different bands (the Lapband [Bioenterics, Carpinteria, CA] and the SAGB [Swedish Adjustable Gastric Band; Obtech Medical, 6310 Zug, Switzerland]) in terms of weight loss and correction of comorbidities, short- and long-term complications, and improvement of quality of life in morbidly obese patients

Summary Background Data: During the past 10 years, gastric banding has become 1 of the most common bariatric procedures, at least in Europe and Australia. Weight loss can be excellent, but it is not sufficient in a significant proportion of patients, and a number of long-term complications can develop. We hypothesized that the type of band could be of importance in the outcome.

Methods: One hundred eighty morbidly obese patients were randomly assigned to receive the Lapband or the SAGB. All the procedures were performed by the same surgeon. The primary end point was weight loss, and secondary end points were correction of comorbidities, early- and long-term complications, importance of food restriction, and improvement of quality of life.

Results: Initial weight loss was faster in the Lapband group, but weight loss was eventually identical in the 2 groups. There was a trend toward more early band-related complications and more band infections with the SAGB, but the study had limited power in that respect. Correction of comorbidities, food restriction, long-term complications, and improvement of quality of life were identical. Only 55% to 60% of the patients achieved an excess weight loss of at least 50% in both groups. There was no difference in the incidence of long-term complications.

Conclusions: Gastric banding can be performed safely with the Lapband or the SAGB with similar short- and midterm results with respect to weight loss and morbidity. Only 50% to 60% of the

patients will achieve sufficient weight loss, and close to 10% at least will develop severe long-term complications.

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The prevalence of obesity, and especially of morbid obesity, is increasing in most Western countries. Comorbidities commonly associated with obesity include diabetes, cardiovascular and respiratory disease, dyslipidemia, degenerative joint disease, stress incontinence, and various types of cancers among others, and are responsible for a reduced life expectancy and an impaired quality of life. Conservative therapy is largely ineffective in producing maintained weight loss in the morbidly obese patients, and surgery is therefore increasingly considered as the only available option for these patients. Until approximately 10 years ago, many patients and physicians regarded bariatric surgery as a dangerous tool, because it required a large laparotomy and was associated with a relatively high risk of complications. Since laparoscopic techniques are available, however, the number of patients referred for surgery has been increasing constantly. In Europe, this was largely the result of the development by Belachew of laparoscopic adjustable gastric banding (GB), first reported by Cadière and Morino in 1994.^{1,2} Within a few years, gastric banding became the technique of choice for many surgeons in Europe and Australia, with high initial success rates, very low perioperative morbidity, and almost no mortality.^{3–9} It soon became apparent, however, that sufficient weight loss (ie, an excess weight loss of at least 50%) could not be achieved in every patient after GB, and that a number of complications arose after some time such as pouch dilatation and slippage, band erosion, esophageal dilatation, leaks, and infections. If the results generally reported are not excellent, but acceptable for a purely restrictive procedure,^{10–18} some very poor results have also been reported by isolated groups,^{19,20} with very high rates of long-term complications and/or poor weight loss.

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Since the introduction of laparoscopic GB, 2 bands mainly have been available. The Lapband (Bioenterics, Carpinteria, CA) was used since 1994, and the SAGB (Swedish Adjustable Gastric Band; Obtech Medical, 6310 Zug, Switzerland) was used since 1996. Both bands were used before in open surgery. So far, few attempts have been made at comparing these 2 devices, and conflicting results have emerged from small, nonrandomized studies with short follow up.^{21–25} The aim of our study was to compare, in a prospective, randomized fashion, the results of GB for obesity with the Lapband or the SAGB in terms of weight loss, correction of comorbidities, food restriction, complications, and improvement of quality of life.

PATIENTS AND METHODS

Between December 1998 and June 2002, after full preoperative evaluation by a multidisciplinary team specialized in the management of morbid obesity, all the patients scheduled for laparoscopic GB were asked to participate in this study. Preoperative evaluation was performed by an internist–endocrinologist specialized in the management of obesity, a dietitian, a psychiatrist with special interest in the management of eating disorders, and a bariatric surgeon. Many patients were also evaluated by a pneumologist if their medical history suggested sleep apnea syndrome or obesity-related hypoventilation syndrome. Cardiac evaluation was performed by a cardiologist if deemed necessary. All the patients were submitted to preoperative esophagogastroduodenoscopy and upper abdominal echography. Most patients were also submitted to 24-hour baseline pH monitoring and esophageal manometry, because it became increasingly evident that esophageal complications such as dilatation or reflux could develop after banding. Exclusion criteria were contraindications to laparoscopy, severe reflux disease, redo bariatric surgery, and patient's refusal. Patients with severe reflux were offered Roux-en-Y gastric bypass. The protocol was accepted by the local ethics committee on November 9, 1998. Informed consent was obtained from all patients. Randomization was done using numbered sealed envelopes, which were opened immediately before surgery. To facilitate interim analysis, the envelopes were grouped so that there would be an equal number of patients in each study arm after every 10 patients.

The primary end point was excess weight loss, because this is the first goal of any bariatric procedure. Secondary end points were early and late complications, reoperations, the proportion of patients with an excess weight loss (EWL) of at least 50% (success rate in terms of weight loss), food tolerance, and quality of life as evaluated by the Moorehead-Ardelt quality-of-life scoring system.²⁶ Power calculations suggested that at least 81 patients would be needed in each group to identify a 10% difference in the percentage of EWL, with a power of 80% at the 5% significance level. With the

same power and significance levels, it was also calculated that at least 307 patients would be required in each group to identify a 50% reduction in the long-term complication rates (from 16%, as observed during our early experience [excluding the learning curve], to 8%). We initially planned to include 300 patients over a 3- to 4-year period.

Before the initiation of this study, we had performed laparoscopic GB in 144 patients using the Lapband in 98 and the SAGB in 46. The learning curve was therefore behind us. The same surgeon performed all the procedures. The patients were given a single dose of prophylactic antibiotics (2.2 g amoxicillin clavulanate or 1.5 g cefuroxime) at the induction of anesthesia. Thromboembolic prophylaxis was provided using low-molecular-weight heparin, which started at the induction of anesthesia and was pursued until the end of the fourth postoperative week. The surgical technique has been described in details elsewhere.⁸ Briefly, the procedure was done using 5 trocars and a 45° angled optic. The Lapband was placed using the perigastric technique, which was the technique mostly used when the study began in 1998, and the SAGB was placed following the pars flaccida technique. In all cases, care was taken to place the band above the lesser omental sac. If the lesser sac was entered during dissection, a new retrogastric tunnel was created higher up. The band was left empty at the end of the procedure.

The patients were instructed to follow a semiliquid diet for the first postoperative month. A barium swallow was performed 4 weeks after surgery to verify the correct position of the band. The first band inflation was usually done at the same time. The patients were then instructed to follow a solid diet, to take small bites, to chew well, to eat slowly, to avoid drinking while eating, and to avoid sparkling drinks. Further band adjustments were performed as necessary during follow-up, depending on the patient's weight loss and eating capacities. The maximal capacity of 5 mL for the Lapband and 9 mL for the SAGB was strictly respected in all cases. Follow-up visits were scheduled at monthly intervals during the first semester, every 2 months during the second semester, quarterly the second year, and then biannually. Food tolerance was evaluated by a standardized questionnaire every 3 months during the first year and twice a year later on. This questionnaire evaluated the general satisfaction regarding food tolerance, the degree of difficulty in eating various types of food, and the frequency of vomiting/regurgitation. The Moorehead-Ardelt quality-of-life questionnaire, which evaluates the evolution of self-esteem, physical activity, social life, work, and sexual activity, was administered at 6-months interval. Blood samples were taken at least twice during the first year and at least yearly thereafter. Repeat barium swallows were routinely scheduled after 12 to 18 months, after 3 years, and then every 2 years, if not mandated by an abnormal clinical course.

TABLE 1. Preoperative Characteristics

	Lapband	SAGB	P Value
Weight (range)	116.1 kg (79.4–161)	119.9 kg (87.5–165)	0.10
Body mass index (range)	42.6 kg/m ² (34.4–55.6)	43.4 kg/m ² (34.3–51.6)	0.17
Excess weight (range)	92.5% (54–155)	97.3% (52–137)	0.10
Age	39.5 yr (22–64)	36.3 yr (19–69)	0.04
Comorbidities	82.2%	84.4%	NS

NS indicates not significant.

Early complications were complications arising during the first 30 postoperative days, and late complications were complications occurring later on. Major early complications were life-threatening and/or led to early reoperation. Major late complications were life-threatening and/or led to band removal. Patients whose band had to be removed and/or who were converted to another bariatric procedure were excluded from further weight loss analysis. However, for the purpose of an intention-to-treat analysis, they remained included in the analysis regarding the percentage of patients achieving an EWL of at least 50%, in which they were considered as failures as of the time of band removal or conversion.

The percentage of EWL and body mass index were used to evaluate weight loss. The percentage of patients reaching an EWL of at least 50% (therapeutic success) was also calculated.

Comparisons between groups were made using the Student *t* test or the Mann-Whitney *U* test for continuous variables. The chi-squared test, with Yates correction if necessary, or the Fisher exact test were used for categorical variables as appropriate. Differences were considered significant with $P \leq 0.05$.

RESULTS

A total of 180 patients were included in this study between December 1998 and June 2002, at which time patient recruitment was stopped. At that time, laparoscopic Roux-en-Y gastric bypass had largely replaced GB as the

procedure of choice for morbid obesity at our institution because it provided better results with respect to weight loss. Group A included 90 patients with a Lapband and group B included 90 patients with a SAGB. The preoperative characteristics of the patients did not differ between groups, except for age (Table 1). The mean duration of follow up was 39 months. All the patients have reached the first postoperative year, 157 patients (87.2%) have reached the second postoperative year, and 115 patients (63.8%) have reached the third postoperative year. Follow up of group A and B included respectively 98.9% and 98.9% ($P =$ not significant [NS]) of the patients after 12 months, 96.2% and 93.6% ($P =$ NS) after 2 years, and 98.3% and 93% ($P =$ NS) after 3 years.

The operative and in-hospital data are shown in Tables 2 and 3. There were significantly more early complications (8.8% vs. 0%, $P = 0.01$), and there were more early reoperations (5.5% vs. 0%, $P = 0.06$) in group B than in group A. More bands became infected in group B (4.4% vs. 0%, $P = 0.11$). Excluding complications clearly not related to the band, there was still a significant difference in favor of the Lapband group (6.6% vs. 0%, $P = 0.03$).

The evolution of BMI and EWL are depicted in Figures 1 and 2. There was a more rapid weight loss in the Lapband group, with significant differences up to 18 months postoperatively. At this time, the 2 curves joined, and weight loss was similar later on. Figure 3 depicts the distribution of weight loss among the patients in each group. Again, the percentage of patients with a good or excellent weight loss (EWL $\geq 50\%$) was higher until 18 months in group A, but no significant difference could be noted thereafter. Weight loss was insufficient in slightly over 40% of the patients in each group.

Tables 4 and 5 show the long-term complications in each group. There was no difference between the 2 groups regarding the total number of patients with complications, the incidence of major complications, the overall need for reoperation, or the need for major reoperation.

The quality of life improved in both groups up to 18 months, and remained fairly constant thereafter (Table 6). There was no difference between the 2 groups at any time.

TABLE 2. Postoperative Complications

Complication	Lapband	SAGB
Band infection	0	2
Undetermined fever	0	2
Gastric perforation	0	2
Bronchopneumonia	0	1
Hemorrhage (gallbladder bed)	0	1
Total	0	8
Total (band-related)	0	6

TABLE 3. Comparison of Operative and In-Hospital Data Between Lapband and SAGB

	Lapband	SAGB	P Value
Operative time	74.5 min (40–185)	74.6 min (40–200)	NS
Postoperative stay (range)	2.4 d (1–5)	2.6 d (1–9)	NS
Total morbidity	0 (0%)	8 (8.8%)	0.01
Band-specific morbidity	0 (0%)	6 (6.6%)	0.03
Major complications	0 (0%)	5 (5.5%)	0.06
Mortality	0 (0%)	0 (0%)	NS
Early reoperations	0 (0%)	5 (5.5%)	0.06
Band-related reoperations	0 (0%)	4 (4.4%)	0.11

NS indicates not significant.

Food tolerance was better in the SAGB group during the first year, with less frequent vomiting, but no difference could be detected later on. Comorbidities improved or disappeared in the majority of patients, without any difference between the 2 treatment groups.

DISCUSSION

GB is a purely restrictive bariatric procedure, which involves the creation of a very small proximal gastric pouch by placing a band around the stomach just below the cardia. It was developed in the 1980s with nonadjustable bands of various materials but is currently almost exclusively performed through the laparoscope with an adjustable band. Laparoscopic GB has indeed been shown in a randomized study to be superior to its open counterpart regarding hospital stay and readmissions.²⁷ The operation is relatively short, has a low perioperative morbidity, and maintains the integrity of the digestive tract. Some also consider the adjustability and the easy reversibility of GB as an advantage compared with other procedures.^{11–14,18,28–30} Others have had relatively poor results, with poor weight loss and a high incidence of long-term complications and reoperations.^{19,20,31} Until now, GB has been used essentially by bariatric surgeons in Europe and Australia. In the United States, the Lapband has been approved by the U.S. Food and Drug Administration (FDA) only in June 2001, which has prevented its widespread use before this date.

GB is usually reported to be associated with a low perioperative complication rate and a very low mortality. The mean excess weight loss after 2 or more years is between 45% and 65%.^{7,11–15,17,28–30,32,33} Commonly reported long-term complications are band slippage with or without pouch dilatation, band erosion (migration of the band into the stomach), band or port infection, and leaks from the band, port, or connecting tube. Overall, late morbidity affects between 6% and 25% of the patients in series including more than 100 patients. The frequency of each of these complications varies among series. For instance, band slippage occurs

at rates between 0.6% and 20%, band erosion at rates between 0% and 11%, and leaks at rates between 1.4% and 26%. These late complications lead to reoperations in up to 20% of the patients.^{8–15,17,18,20,25,28–30,32,34}

Two different adjustable bands have mainly been used since the introduction of laparoscopic GB: the Lapband (adjustable silicone gastric banding) and the SAGB. The latter has not yet been approved by the FDA. An abundant literature on laparoscopic GB has been published during the past few years, and most of it refers to these 2 devices. Most authors, however, have used only 1 or the other band. Only small or nonrandomized series including the 2 bands are available, and the follow up is usually short.^{21,22,24,25} This makes comparison of results between the 2 bands very difficult. Hesse et al. compared 79 patients operated with a Lapband with 41 patients implanted with a SAGB successively. They found a significantly higher slippage/pouch dilatation rate (19% vs. 3%) and more port complications (26% vs. 10%) with the Lapband than with the SAGB but no difference in the erosion rates. The mean follow up, however, was only approximately 12 months.²⁵ Another study by Frereng, comparing 821 Lapband patients with 597 SAGB patients, showed a higher incidence of pouch dilatation/slippage with the Lapband (4.1% vs. 0%) but no other difference.²¹ Ponson recently published a study comparing, in a nonrandomized way, 52 patients operated with a Lapband and 49 patients operated with a SAGB. He found no difference between these 2 devices with respect to early and late complications or weight loss. The follow up of less than 1 year, however, was extremely short.²⁴ A last paper published by Miller et al. compared 102 Lapbands with 54 SAGB and showed no difference in weight loss or the incidence of long-term complications after a mean follow up of 28 months.²²

The design of the 2 bands is different. The Lapband is a rigid and relatively narrow (12.5 mm) silicone band. Its inner balloon can be inflated up to 5 mL. It is described as a high-pressure system, because the pressure created within the

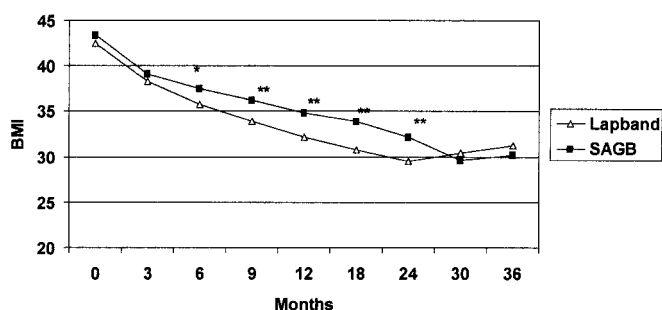


FIGURE 1. Evolution of body mass index over time (* $P < 0.05$, ** $P < 0.001$).

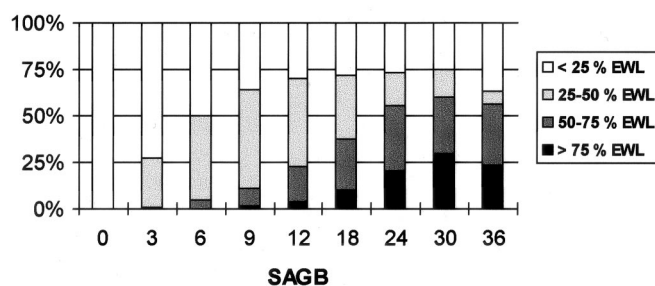
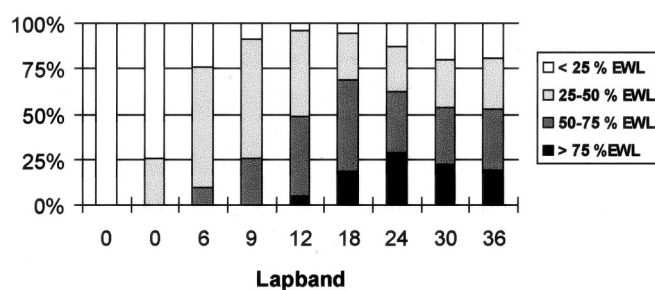


FIGURE 3. Distribution of weight loss over time.

balloon increases rapidly to values well above 150 kPa.¹⁴ It can be placed according to the so-called perigastric technique, like in this study, or with the pars flaccida technique. The latter is increasingly used, and many authors have abandoned the former one because of its association with a higher slippage rate. The SAGB is a soft silicone band and is much wider (23 mm). The balloon can be inflated up to 9 mL. The SAGB is described as a low-pressure system, because even with maximal inflation, the pressure within the balloon remains low.¹⁴ The SAGB is placed according to the pars flaccida technique. Some of the differences between the 2 bands could theoretically account for differences in weight loss and complications. The greater volume of the SAGB could make fine adjustments easier, improve food tolerance, decrease vomiting, and increase weight loss. Because of its larger width, the pressure transmitted by this band on the gastric wall should be lower, and the risk of gastric erosion could be reduced. Inflation of the SAGB, however, creates folds on the inner surface of the balloon, which could result in an uneven distribution of the pressure on the gastric wall and an increased risk of erosion. A wider band also might be more stable, resulting in a reduced slippage rate. The Lapband, with its smooth and narrower inner surface, could present a larger risk of slippage and erosion.

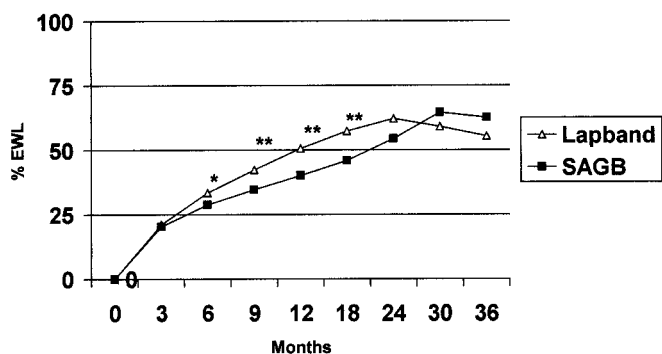


FIGURE 2. Evolution of excess weight loss (EWL) over time (* $P < 0.05$, ** $P < 0.01$).

To our knowledge, the present study is the first prospective, randomized trial comparing the results of GB using the Lapband or the SAGB. The 2 main findings were that early band-related morbidity was higher with the SAGB and that weight loss was initially faster with the Lapband. No difference could be found between the 2 groups regarding weight loss or the overall success rate after 18 months, food tolerance, and improvement of quality of life. Late morbidity and the need for reoperation were also identical. Major reoperation was necessary in nearly 10% of the patients in each group.

As a result of the limited power of our study regarding the analysis of complications, the results in that respect must be interpreted with caution. Whether the differences in early morbidity are really the result of the band is indeed not clear. Two complications (bronchopneumonia and hemorrhage from the gallbladder bed) are certainly not related to the type of band. In the 2 patients with gastric perforation, poor surgical technique (thermal injury by monopolar cautery, transfixing suture) may well be responsible rather than the band itself. The issue of infection is of greater concern. Two patients developed early band infection, necessitating band removal after 3 and 6 weeks. Two other patients required antibiotics for unexplained fever during the early postoperative days and developed band erosion 8 weeks (before any adjustment), respectively, 6 months after surgery. One can assume that these 2 patients had in fact early, unrecognized band infection, which later led to band erosion. We have no explanation for this difference in infection rates. Intraoperative differences in sterility precautions should not be responsible, because the same surgeon implanted all the bands.

TABLE 4. Long-term Complications

Type of Complication	Lapband	SAGB	P Value
Leak (port or tubing)	2	0	NS
Leak (band)	0	1	NS
Minor port-related complication	1	3	NS
Port infection	0	1	NS
Psychologic intolerance	0	2	NS
Band infection	0	0	NS
Esophageal dilation	2	2	NS
Pouch dilatation/slippage	4	0	0.11
Erosion	6	7	NS
Total patients with complications	17	16	NS
Total with major complications	8	11	NS

NS indicates not significant.

Great care was taken when opening the package of the band, and this was always done immediately before inserting the band into the abdomen. If only the clearly band-related or possibly band-related complications are considered, this randomized study shows a significant difference between the 2 devices in favor of the Lapband. Again, the risk of a type 2 error is significant as a result of the limited number of patients.

Weight loss was slightly faster with the Lapband. This difference was probably the result of the fact that, during follow up, early adjustments of the Lapband were more important. Indeed, the first band adjustment was usually made after 1 month with 2 to 3 mL for the Lapband and 3 mL for the SAGB, and further adjustments with 0.1 to 1 mL for both devices. This reflects into the better early food tolerance and

TABLE 5. Long-term Reoperations

Type of Reoperation	Lapband	SAGB	P Value
Port removal	0	1	NS
Band removal	1	3	NS
Band replacement	1	0	NS
Port repositioning	1	3	NS
Placement of new port	0	1	NS
Correction of leak	3	0	NS
Conversion to Roux-en-Y gastric bypass	8	9	NS
Total late reoperations	14	19	NS
Total patients with late reoperation(s)	13	14	NS
Total patients with major late reoperation	8	10	NS

NS indicates not significant.

TABLE 6. Improvement of Quality-of-Life According to the Moorehead-Ardelt Questionnaire*

	SAGB	Lapband	P Value
6-mo	1.28	1.41	NS
12-mo	1.50	1.59	NS
18-mo	1.65	1.87	NS
24-mo	1.83	2.03	NS
30-mo	1.86	1.81	NS
36-mo	1.76	1.71	NS

*The score can vary between -3 (important worsening in all aspects) and +3 (important improvement in all aspects).

NS indicates not significant.

less frequent vomiting in patients with the SAGB. After 18 months, however, no difference in weight loss, or in food tolerance, could be detected.

Overall, there was no significant difference between the 2 groups regarding the incidence of long-term complications. Minor port-related complications occurred in 3% of the cases in both groups and could always be treated under local anesthesia.

Pouch dilatation/slippage was seen only in the Lapband group, although the difference was not significant. This is consistent with the literature in which slippage rates up to 20% are reported after the Lapband compared with 0% to 5.6% with the SAGB.^{8,10-15,18,25,28,30,32,34} The perigastric technique used in this study has probably played a role, and many authors have now abandoned it in favor of the "pars flaccida" technique, because the latter is associated with a lower slippage rate. As stated here, slippage may also be influenced by differences in the design of the bands.

Band erosion occurred at a relatively equal high frequency in both groups (6.6% vs. 7.7%) compared with the literature.^{6,10-15,18,20,25,30,32,34} Apart from the 2 patients with early, unrecognized band infection, we have no explanation for this high incidence. In no case was the band overinflated. Three erosions were diagnosed incidentally during endoscopy performed in the setting of another study (intended to evaluate the effects on GB on gastroesophageal reflux disease and esophageal motility). These 3 patients were totally asymptomatic. Because only approximately 40 patients underwent endoscopy, an even higher incidence of band erosion in the entire series is not excluded. Some authors recently pointed out that the low-pressure system of the SAGB could decrease the risk of erosion.¹⁴ With equal rates of erosion, our results do not support this assumption. In fact, the only relevant pressure in terms of erosion is the pressure at the interface between the band and the gastric wall, which nobody has studied yet.

This study has a number of limitations. First, the number of patients was determined to assess for differences in weight loss, and not in the rate of early or long-term complications. To assess for differences in the number of complications with the same power, several hundreds of patients would have been required in each group, as stated in the "Patients and Methods" section. We had initially planned to include at least 300 patients over a 3-year period. Since laparoscopic Roux-en-Y gastric bypass has progressively become our procedure of choice for morbid obesity over the past few years, the number of banding procedures has decreased dramatically to only 15 in 2002, and we had to close the study prematurely. As already mentioned, the risk of type 2 error is high when comparing early or late morbidity. A second limitation is the length of follow up, which, with a mean of 39 months, is less than the minimum standard of 60 months considered as adequate to report on the results of bariatric procedures. We will continue to follow these patients and will report 5-year results when they are available. On the other hand, 1 strength of our study is that the same surgeon has operated on all the patients, with the learning curve behind him. Technical differences should not account for any difference in results.

In conclusion, no major significant difference was found between the 2 devices, except for a higher rate of early band-related complications, and especially infections with the SAGB. GB with either the Lapband or the SAGB provides good results (EWL of at least 50%) in 55% to 60% of the patients after 2 to 3 years, and the risk of long-term severe complications appears to be the same. Approximately 25% of the patients in each group have very good results with an EWL of more than 75% and no complication. Unfortunately, 40% to 45% of the patients fail to achieve sufficient weight loss, partly because they develop complications. With time, the frequency of late severe complications is likely to increase. These results need to be confirmed by longer follow up and in a study involving a much larger group of patients regarding early and long-term morbidity. Meanwhile, GB can still be considered as an option for the treatment of morbid obesity and it can be performed safely. The choice of the band is probably of relatively low significance. The patients, however, should be completely informed about the limitations of gastric banding in producing weight loss, and about the risks of short- and long-term complications requiring reoperation and possibly removal of the band with conversion to another procedure. They should also be well informed about alternative bariatric operations and be given the chance to participate in the decision about the best procedure suited for them. The surgeon should be offering the alternative procedures him- or herself, or be willing to refer the patient to another surgeon if necessary.

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